REMARKS

Of claims 1-41 previously presented, claims 11, 12, and 14 were withdrawn from consideration pursuant to an election requirement and claims 15 and 30 were previously canceled, leaving claims 1-10, 13, 16-29, and 31-41 for consideration on the merits. Applicants continue to assert that at least independent claims 1, 26, and 33 are generic. In view of the amendments and remarks presented herein, reconsideration and allowance of all pending claims are respectfully requested

As an initial point, Applicants submit that the above-presented claim amendments are fully supported by the original specification. Independent claims 1, 26, and 33 are amended to more clearly describe the structure and operation of the collapse actuator. Specifically, the claims now specify that the collapse actuator includes a detachable distal end that is received within a distal aperture in the closure component and extends distal to the distal aperture. In addition, the amended claims now specify that the detachable distal end of the collapse actuator is operable to pass proximally through the distal aperture and the collapsed closure component. Support for this claim language is found in the specification as originally filed at page 6, lines 7-10; page 9, lines 3-7; page 9, line 23 through page 10, line 5; and Figs. 2-5. Applicants also note that claims 16, 17, and 18 are amended herein to be consistent with the changes to claim 1, from which they ultimately depend. Finally, claim 13 is amended herein to correct a typographical error. Accordingly, consideration and entry of these claim amendments are respectfully requested.

Turning to the Office action, claims 1-10, 13, 16-29, and 31-41 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,964,782 ("Lafontaine") in view of U.S. Patent No. 6,334,865 ("Redmond") and U.S. Patent No. 6,270,515 ("Linden"). Applicants traverse this ground of rejection.

As an initial point, Applicants submit that the proposed combination of Lafontaine, Redmond, and Linden is improper, and therefore the obviousness rejections based thereon must be withdrawn. First, Redmond and Linden teach away from each other and therefore there combination is improper. More specifically, Redmond teaches a device which functions to provide a barrier at an opening in a blood vessel wall prior to injection of a hemostatic flowable

material. Thereafter, the entire device of Redmond, including the barrier and the barrier actuator coupled thereto, is completely removed from the site. Linden, on the other hand, teaches a device for permanently placing a sleeve or barrier at the site of an opening. Contrary to the device of Redmond, which removes the barrier and barrier actuator, the expandable balloon of Linden is ultimately deflated and removed, leaving the sleeve positioned in the defect site. Consequently one of ordinary skill in the art would not be motivated to modify Redmond, which teaches a device in which a barrier is permanently coupled to an actuator, by Linden, which teaches a device in which the barrier is detachable from the actuator, since these two references clearly teach away from one another.

The motivation to combine the proposed combination is further lacking because it would render the Redmond device unsatisfactory for its intended purpose. Under MPEP §2143.01, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP §2143.01 (*citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). The Office action proposes to modify the device of Redmond, which permanently attaches the barrier to the actuator to provide a temporary barrier that is later withdrawn from the patient, with Linden, which detaches a sleeve from an actuator so that the sleeve remains in a patient. Such a modification would render the Redmond device incapable of performing its intended purpose of retrieving the barrier from the patient. Consequently, Applicants respectfully submit that these references are improperly combined and that the rejections based thereon should be withdrawn.

Even if the above improprieties of the proposed combination are ignored, the cited prior art fails to disclose or suggest each element of the claims as amended. More specifically, amended independent claim 1 specifies a closure device for closing an opening in a body cavity including an elongate delivery member and a closure component removably connected to the delivery member. The closure component includes a collapsible backing movable between a non-collapsed position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape. A collapse actuator is releasably coupled to the collapsible backing and is operable to move the collapsible backing from the non-collapsed position to the collapsed

position. Amended claim 1 also now recites that the collapse actuator includes a detachable distal end that is received within a distal aperture in the closure component and extends distal to the distal aperture when the closure component is in the non-collapsed position. Further, amended claim 1 now recites that the detachable distal end of the collapse actuator is operable to pass proximally through the distal aperture and the collapsed closure component.

Similarly, amended independent claim 26 specifies a method of closing an opening in a body including inserting a closure component having a collapsible pile backing distally through the opening. The pile backing initially has a non-collapsed position in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing. The method further includes withdrawing the closure component proximally relative to the opening such that the tissue engaging hooks engage tissue adjacent the opening. The method of amended claim 26 now also requires applying proximally directed force to a collapse actuator that is releasably coupled to the collapsible pile backing and has a detachable distal end received within a distal aperture of the collapsible pile backing, the detachable distal end extending distal to the distal aperture, thereby to collapse the collapsible pile backing to a collapsed position in which the backing center portion is moved proximally toward the backing periphery to form a generally disc shape. Further, the method of amended claim 26 now requires disconnecting the collapse actuator from the collapsible pile backing by applying additional proximally directed force on the collapse actuator, thereby causing the detachable distal end of the collapse actuator to pass proximally through the distal aperture and the collapsed pile backing.

Also similar to claim 1, amended independent claim 33 specifies a closure device for closing an opening in a body cavity including an implantable closure component having a longitudinally collapsible backing movable between a non-collapsed position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape. A collapse actuator is releasably coupled to the collapsible backing and operable to move the collapsible backing from the non-collapsed position to the collapsed position. Amended claim 33 also now recites that the collapse actuator includes a detachable distal end that is received within a distal

aperture in the closure component and extends distal to the distal aperture when the closure component is in the non-collapsed position. Further, amended claim 33 now recites that the detachable distal end of the collapse actuator is operable to pass proximally through the distal aperture and the collapsed closure component.

The proposed combination of Lafontaine, Redmond, and Linden fails to disclose or suggest the closure device and method as currently claimed. The Examiner acknowledges that the primary Lafontaine reference fails to disclose or suggest: (1) a backing having a conical shape that is collapsible into a disc shape; and (2) a collapse actuator releasably coupled to the collapsible backing. The Examiner alleges that Redmond discloses a conical backing that is collapsible to a disc shape, but does not rely on Redmond for disclosing a collapse actuator. Instead, the Examiner alleges that Linden teaches manipulating a collapse actuator 524 releasably coupled to a collapsible backing 512 and operable to move the collapsible backing, and disconnecting the collapse actuator from the backing. It is not seen that Linden discloses the collapsible actuator of the closure device and method as currently claimed, specifically, a collapse actuator that is releasably coupled to a collapse backing, the collapse actuator including a detachable distal end received with in a distal aperture of the closure component and positioned distal to the distal aperture, and the detachable distal end operable to pass proximally through the distal aperture and the collapsed closure component.

Instead, Linden discloses a septal defect closure device that includes a mesh sleeve 512 placed over an expandable balloon located at the distal end 522 of a catheter 520 (Col. 10, lines 57-60 and Figs. 17 and 18). As shown in Fig. 19, the balloon 524 is inflated after delivery to the defect site, allowing the mesh sleeve 512 to contact the septal tissue 505, as shown in Fig. 20 (Col. 10, lines 64-66). Also referring to Fig. 20, after deployment and attachment of the sleeve 512, the balloon 524 is deflated and removed from the site of the defect 506 (Col. 11, lines 12-14).

In the current Office action, the Examiner has equated the collapse actuator and collapsible backing of the present invention to the expandable balloon 524 and sleeve 512 of Linden. As an initial point, Applicants assert that such an analogy is not feasible given that the expandable balloon 524 of Linden functions in a manner completely contrary to that of a collapse actuator. Specifically, as described above, the expandable balloon of Linden 524

functions to expand the sleeve 512 within an opening, thereby allowing the sleeve to attach to tissue. The expandable balloon 524 of Linden does not collapse the sleeve, as any collapse actuator would be expected to function, including the collapse actuator of the presently claimed invention. In turn, the expandable balloon cannot be equated to a collapse actuator. Further, while the expandable balloon 524 of Linden can be described as releasably coupled to the sleeve 512, unlike the subject matter of amended independent claims 1, 26, and 33, the expandable balloon 524 of Linden does not include a detachable distal end received with in a distal aperture of the closure component or sleeve and positioned distal to the distal aperture. Moreover, as the expandable balloon 524 of Linden includes no such detachable distal end, it cannot operate to pass the detachable distal end proximally through the distal aperture and the collapsed closure component, as also required by amended independent claims 1, 26, and 33

In view of the foregoing, the proposed combination of Lafontaine, Redmond, and Linden fails to disclose or suggest each element of the amended claims, specifically, a collapse actuator including a detachable distal end received with in a distal aperture of the closure component and positioned distal to the distal aperture, and the detachable distal end operable to pass proximally through the distal aperture and the collapsed closure component, and therefore, the obviousness rejection based thereon must be withdrawn.

Claims 2-10, 13, 16-25, 27-29, 31-32, and 34-41 all depend directly or indirectly from independent claims 1, 26, and 33, and therefore, are patentable over the proposed combination of references for the same reasons presented above.

Regarding the rejection asserted against claims 17-21, the Examiner alleges that Redmond discloses structure responsive to the claimed collapse actuator by stating, "Redmond et al teaches a deformable hook, or wire, 22 at the distal end of an [sic] collapse actuator 20 that is received within a distal aperture in the closure component 26 and grasps the closure component and moves a distal end of the closure component to a more proximal position to collapse the closure component under proximally directed force applied to the elongate member and wherein the deformable hook is located distal of the distal aperture in the closure component 22 ... the deformable hook 22 capable of deforming to pass trough the distal aperture in the closure component 22 after the closure component 22 has moved to the collapsed position under continued application of proximally directed force on the collapse actuator 20." Applicants

respectfully submit that the Examiner appears to have misinterpreted the Redmond reference. Specifically, the barrier actuator 22 of Redmond is permanently coupled to the barrier 26, and therefore is not responsive to the releasable collapse actuator. More specifically, if one considers the barrier actuator 22 to be the collapse actuator and the barrier 26 to be the collapse backing, then it is evident that the barrier actuator 22 is not releasably coupled to the barrier 26 as required in the claims. Instead, as described in the Redmond specification, after hemostatic flowable material has been injected at the site, barrier actuator 22 is extended to move barrier 26 from the deployed configuration (collapsed) of Fig. 2 to the undeployed configuration (extended) of Fig. 1 (Col. 7, lines 9-13). Thereafter, the entire barrier assembly, including the barrier actuator 22 and barrier 26 are withdrawn from the tissue track, as shown in Fig. 5 (Col. 7, lines 14-15). Accordingly, the barrier actuator 22 of Redmond is not responsive to the claimed releasable collapse actuator having a detachable distal end operable to pass proximally through the distal aperture and the collapsed closure component, thereby releasing the detachable distal end and actuator from the collapsed closure component. In turn, the proposed combination of Lafontaine, Redmond, and Linden fails to disclose or suggest each element of claims 17-21, and therefore, the obviousness rejection based thereon must be withdrawn.

CONCLUSION

It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.

If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,
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